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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/743,357	12/22/2003	Walter L. Carpenter	P-11209.05	9331

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EXAMINER

DEAK, LESLIE R

ART UNIT	PAPER NUMBER
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3761

DATE MAILED: 05/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/743,357

Applicant(s)

CARPENTER ET AL.

Examiner

Leslie R. Deak

Art Unit

3761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-41 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 27-29 is/are rejected.
- 7) ☒ Claim(s) 2-26 and 30-41 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 June 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 3/04, 2/05, 11/05.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1, 27, and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,890,316 to Rawles et al in view of US 5,540,653 to Schock et al.

In the specification and the figures, Rawles discloses the device substantially as claimed by applicant. In particular, Rawles discloses a tubing set including a priming system for priming an extracorporeal blood circuit with venous and arterial lines. The circuit or tubing set 20 comprises a perfusion circuit 21 and a priming circuit 25 continuously coupled to the arterial line 24 and venous line 22, wherein the priming circuit corresponds to applicant's claimed pre-bypass loop (see FIGS 2-4, columns 5-6). The tubing set further comprises a prime line 27 that connects priming fluid containers 44, 45 to the main fluid circuit.

Applicant claims a "means for controlling" the flow of the prime solution from the source to the fluid circuit, but fails to define the means for controlling in the specification. Examiner has interpreted the "means for controlling" to include any device that has the capacity to control the fluid flow through a tubing line. Rawles discloses that the prime line 27 comprises valves 37, 38a, 38b, 39a, and 39b to regulate or control flow through the circuit and priming line (see column 6, lines 30-39). Therefore, the Rawles

Art Unit: 3761

disclosure meets the limitations of the claim with regard to a "means for controlling" flow.

Rawles further discloses that the circuit has valves or purge ports that allow for the de-airing of the system during priming. Further, Rawles discloses that the system may incorporate specialized air vents of an active air removal system (see column 7, lines 10-30).

Rawles fails to disclose that the priming system comprises a circuit holder with a vertical mast and hanger with support arm. However, Schock discloses a preassembled bypass circuit with a priming fluid source 48 that primes the fluid circuit 14/20. The priming fluid source is suspended from support structure 50 attached to vertical pole 48 above circuit 14/20, allowing gravity to push the priming fluid from source 48 through priming line 22, and into the fluid circuit, with valve 36 acting as purge port (see column 6, lines 1-44, FIG 1).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the priming circuit disclosed by Rawles with a circuit holder or support structure as disclosed by Schock, in order to allow for easy and quick gravitational priming of the fluid circuit with complete air removal, as taught by Schock.

With regard to claim 28, Schock discloses a cardiopulmonary bypass circuit with a blood pump 10 that draws blood through the circuit, a venous air removal device and arterial filter (trap/filter 16) with an inlet 34 at the top of the device and an outlet 44 at the bottom of the device, and oxygenator 12 (see FIG 1). Schock does not disclose that

Art Unit: 3761

the filter/trap and blood pump are directly connected. However, the pump disclosed by Schock acts to move blood through the circuit, just as the pump claimed by applicant. It has been held that rearranging parts of an invention involves only routine skill in the art. See MPEP § 2144.04. Absent any showing of criticality of the location of the pump with regard to the air trap and or filter, examiner considers the location of the parts to be a mere rearrangement of the parts of the device, since the device disclosed by Schock functions in the same manner claimed by applicant. With regard to the addition of the elements disclosed by Schock to the tubing set disclosed by Rawles, Rawles specifically teaches that the disclosed tubing set features standardized quick-connect connectors that may be customized to adapt to the needs of other blood handling systems in the art (see column 2, lines 50-63). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to add the components disclosed by Schock to the blood handling tubing set disclosed by Rawles, since Rawles specifically discloses that his system is designed to accommodate such systems.

Double Patenting

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct

Art Unit: 3761

from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 27-29 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 10, and 18 of copending Application No. 10/743,373 in view of US 6,890,316 to Rawles and US 5,540,653 to Schock et al.

This is a provisional obviousness-type double patenting rejection.

The '373 application claims the extracorporeal blood circuit instantly claimed by applicant, but fails to claim the priming circuit of the instant application. Rawles and

Art Unit: 3761

Schock disclose the priming circuit of the instant application (see rejection above), and Rawles specifically discloses that the priming circuit of his invention is configured to support various extracorporeal blood circuits in order to provide a system with a low priming volume that purges air during priming and maintains sterility during priming. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to add the priming circuit disclosed by Rawles and Schock to the extracorporeal blood circuit claimed in the '373 application in order to provide a blood circuit with low priming volume and increased sterility, as taught by Rawles and Schock.

Allowable Subject Matter

5. Claims 2-26 and 30-41 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims, as well as correcting the 35 USC 112 rejection above.

6. The following is a statement of reasons for the indication of allowable subject matter: The prior art fails to disclose or suggest the apparatus and method claimed by applicant. In particular, the prior art fails to disclose a device and method for priming a tubing set comprising a tubing set and blood treatment components as claimed by applicant wherein the tubing set and components are secured to a mounting apparatus with the relative elevations claimed by applicant, along with the other steps and limitations of the claims. While the prior art teaches that it is beneficial to suspend the

Art Unit: 3761

priming solution at a height above the circuit, the prior art fails to teach the relative elevations of the remainder of the treatment components (oxygenator, pump, arterial filter, air removal device) claimed by applicant. Furthermore, applicant discloses that his particular arrangement is necessary to reduce prime volume and to create an easy to use tubing and connection system. Therefore, the instant claims are patentable over the prior art.

Conclusion

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

- a. US 6,299,589 Utterberg
 - i. Tubing set for dialysis devices
- b. US 6,607,698 Spears et al
 - ii. Method and tubing set for generalized extracorporeal support
- c. US 6,824,524 Favre
 - iii. Tubing for an extracorporeal circuit

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie R. Deak whose telephone number is 571-272-4943. The examiner can normally be reached on M-F 7:30-5:00, every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3761

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Leslie R. Deak
Patent Examiner
Art Unit 3761
26 April 2006

TATIANA L. UKAEVA
SUPERVISOR, PRIMARY EXAMINER

